



1653

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S) : Rogelj, et al.  
SERIAL NO. : 10/002,698  
FILED : December 5, 2001  
FOR : Inhibition of Cell Surface Protein Disulfide Isomerase  
GROUP ART UNIT : 1653  
Examiner : David Lukton

Commissioner for Patents  
Mail Stop Non-Fee Response  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**Response to Restriction Requirement**

In response to the Examiner's correspondence dated March 11, 2004, pursuant to the Examiner's restriction requirement in the above-referenced patent application, Applicants provisionally elect with traverse to prosecute the invention of group 3, consisting of claims 14-15 which are directed to a method of treating a viral infection using the compound of claim 8. In the alternative, and in the interest of an efficient examination of this application, Applicants respectfully request the Examiner to give consideration to examining all of the claims of the instant application, namely claims 9-15 and 19-21 together for purposes of expediting prosecution of the present application.

Notwithstanding Applicants' election, Applicant respectfully traverses the Examiner's requirement for restriction. Applicant respectfully requests the Examiner reconsider his restriction requirement. Applicant respectfully submits that prosecution of all of the originally filed claims should not be restricted to the elected invention, for the reasons which are set forth hereinbelow.

According to M.P.E.P. §803, restriction by the Examiner of patentably distinct inventions is proper if the claimed inventions are independent and a *serious burden* would be placed on the

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Examiner if restriction was not required. Applicant respectfully submits that the presentation of all of the originally filed claims would not place such a serious burden on the Examiner as to require restriction. All of the originally filed claims are related, though patentably distinct chemical compounds, and related methods of using these compounds as PDI inhibitors.

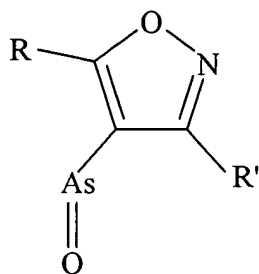
Although the claimed invention groups are generally patentably distinct from each other, Applicant respectfully submits that any search the Examiner would need to conduct in examining the instant application would not be unduly burdensome. Moreover, the examination of all of the originally filed claims in the instant application would not place such a serious burden on the Examiner as to require restriction.

Applicants understand the general policy considerations for the Patent Office's requirement for restriction in certain instances. In this instance, however, those considerations do not weigh in favor of restricting the inventions here. In determining the appropriateness of restriction, one must also consider the countervailing consideration that, in each instance, Applicant wishes the Patent Office to examine his or her application with a certain degree of "administrative efficiency" and wishes to have patent claims issue which reflect the breadth of his or her invention.

Applicants respectfully submit that the originally filed claims are sufficiently narrow to allow the Examiner to determine patentability without being subjected to the serious burden referred to in M.P.E.P. §803. Consequently, Applicant respectfully requests that the Examiner withdraw the restriction requirement in its entirety.

However, in the event that the Examiner determines to maintain the restriction requirement, Applicants respectfully submit that the election of invention group 3, claims 14-15, drawn to a method of treating a viral infection utilizing the compounds of claim 9 is sufficient for purposes of examining the present application. Applicants also respectfully submit that the

Examiner's requirement for Applicants to elect a species, i.e. a single compound is inappropriate here because claims 14-15 already exhibit unity of invention inasmuch as the compounds of claim 9 are directed to structurally similar compounds having an identical core (see below) and similar pharmacological activity as anti-viral agents having a common utility.



### Compounds of Claim 9

It is well settled that claims to compounds all having an identical nucleus with a large variety of substituents, where all of the compounds have a common utility as in the present case, are part of a single invention (unity of invention). The alleged burden of searching the invention in different fields of search and different search classifications plays absolutely no role in the determination of unity *vel non*. See, *In re Harnisch*, 206 USPQ 300 (CCPA, 1980). There is a unity of invention based upon the identity of the central nucleus in all compounds, especially if all of the compounds have a common utility and function and, therefore, belong to a common, recognized *genus*, and have a community of properties. See, *ex parte Brouard*, 201 USPQ 538 (Bd. App., 1976).

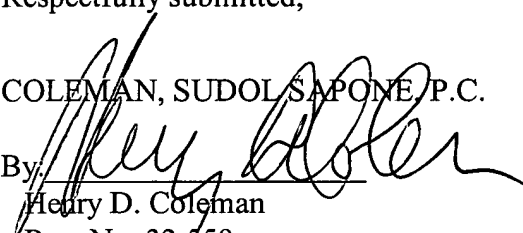
The determination of unity of invention does not require that there be a community of properties (although in the present application, this happens to be the case), as long as the covered compounds have a common nucleus (as in the case of the isoxazole nucleus here) which would exhibit certain characteristics. See, *ex parte Taylor*, 167 USPQ 637 (Bd. App., 1969).

Thus, based upon the foregoing, the law is unequivocal that as long as all of the claimed compounds in an application have the same common nucleus, those compounds (of method claims 14-15) represent a single invention *regardless of the number and type of substituents on that common nucleus* and the alleged burden of searching the invention in different fields of search. It is also clear that different search classifications play no role in the determination of unity of invention under the law. Thus the argument for unity of invention within the group 3 invention is particularly cogent here and consequently, it is respectfully submitted that the Examiner's request for Applicants to elect a single species should be withdrawn.

The Examiner is cordially requested to call the undersigned attorney if the Examiner believes that a telephonic discussion may materially advance the prosecution of the instant application in any way. No fee is due for the presentation of this response. A supplemental information disclosure statement is enclosed as are copies of the five cited references.

Respectfully submitted,

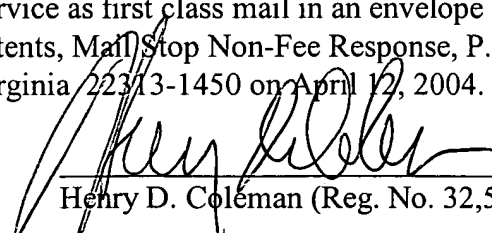
COLEMAN, SUDOL SAPONE P.C.

By:   
Henry D. Coleman  
Reg. No. 32,559  
714 Colorado Avenue  
Bridgeport, Connecticut  
(212) 679-0090

Dated: April 12, 2004

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner of Patents, Mail Stop Non-Fee Response, P.O. Box 1450, Alexandria, Virginia 22313-1450 on April 12, 2004.

  
Henry D. Coleman (Reg. No. 32,559)

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